



ISPE Nordic

Invitation to
The Annual Meeting 2007

Pharmaceutical Manufacturing
15 November 2007
Copenhagen – Denmark



**Nordic
Affiliate**

ENGINEERING
PHARMACEUTICAL
INNOVATION

ISPE Nordic Annual Meeting 2007 – 15 November 2007

Welcome to ISPE Nordic's Annual Meeting 2007!

We look forward to seeing you at the main event of the year for all members of ISPE Nordic - our Annual Meeting. This year the meeting takes place in Copenhagen.

The Annual Meeting is the opportunity to meet and network with the broadest representation of our more than 1,000 Nordic members from pharmaceutical and biotech companies, suppliers, engineering & consulting companies, academia and regulators within ISPE Nordic as well as our international speakers. We are especially pleased to have high level presentations from both regulatory authorities as well as some of the largest pharmaceutical companies in the Nordic region.

ISPE Nordic has grown significantly the past years and we are now more than 1,000 members! This size of the organisation makes it possible to offer more interesting and attractive activities, obvious already from the enclosed programme.

The Annual Meeting is a full day event but still provides a number of options for you. Stay for the day, or just pick the items that suit you best:

- Participate in the Conference on "Pharmaceutical Manufacturing".
- Continue with the Annual General Meeting for ISPE Nordic, with a first launch of the 2008 programme, reports from the Board, and election of Board Members
- Participate in GAMP Nordic Annual Meeting.
- Conclude the evening with the Social events, Cocktail Reception and the Annual Meeting Dinner – the place to meet your peers from the industry.

Welcome to a full day of attractions!

The dinner party with entertainment after the annual meeting we pursue to develop to the Nordic Pharma and Biotech industries' Social Event of the Year. You just have to be there, because everyone else will come. Previous year's Annual Dinner in Stockholm was very well received and included great entertainment from two singers. We have as a tradition - the possibility for you to host a dinner table and invite your colleagues or your customers to the dinner. Please see the enclosed registration form for more details. Of course you still can participate as an individual in the programme, too!

Please note that on 13 and 14 November there is the second pan-European PAT Science Conference (EuPAT2) on the theme "Scientific Progress Underpinning Process Analytical Technology (PAT)". For details about this, and other coming events, please visit our website: www.ispe.org/nordic.

Sincerely,
ISPE Nordic



Charlotte Enghave
Chairman



VENUE

Radisson SAS Scandinavia Hotel
Amager Boulevard 70,
DK-2300 Copenhagen S
Tel +45 38 15 65 00
Fax +45 38 15 65 01
www.radissonsas.com

The hotel is located near the centre of Copenhagen, approx. 11 km from Copenhagen Airport and approx. 2 km from Copenhagen Central Station.



HOTEL ACCOMMODATION

A number of rooms have been prebooked at the hotel at a special rate of DKK 1695 per night including breakfast. Please book directly with the hotel, using the enclosed hotel booking form.

TABLE TOP EXHIBITION

The conference will include a table top exhibition. Please use the registration form to book a table.

SPONSOR TABLES AT THE ANNUAL MEETING DINNER

You will be able to reserve a table for eight persons and invite special guests to join you at the annual meeting dinner. ISPE membership is not required for dinner guests. Your guests may also attend the day conference at a special conference fee of Euro 220. Please use the registration form to book a table.



CONFERENCE PROGRAMME – PHARMACEUTICAL MANUFACTURING – 15 NOVEMBER 2007

- 08:00 – 09:00** **Registration**
- 09:00 – 09:10** **Welcome & Introduction**
Charlotte Enghave, PhD, Senior Consultant, NNE Pharmaplan, Chairman ISPE Nordic
- 09:10 – 09:50** **Establishing an FDA Facility in Brazil**
Henrik Friese, Corporate Vice President, Novo Nordisk A/S, Denmark
- Key drivers for the project
 - The story
 - Lessons learned
- 09:50 – 10:30** **Biogen Idec's Hillerød Bulk Manufacturing Facility**
Craig Beasley, Director of Manufacturing, Biogen Idec International, Denmark
- Project overview
 - Safety as a priority
 - Leveraging past experience to ensure efficiency and flexibility
- 10:30 – 11:00** Coffee Break / Table Top Exhibition
- 11:10 – 11:50** **When is the right time to establish a new production facility**
Peter Vilby, Chief Operating Officer, CMC Biopharmaceuticals A/S, Denmark
- Use of conceptual design to postpone investments as long as possible, and still have the facility ready when needed
 - Fast and cost effective facility establishment, utilizing 3D and modular design
 - Case story – use of the tools in real life
- 11:50 – 12:30** **Genmab's clinical and commercial supply strategy**
Torben Lund Hansen, PhD, Vice President,
Head of Manufacturing & Preclinical Safety, Genmab A/S, Denmark
- Evaluation of suppliers
 - Critical contractual issues
 - Risk sharing
- 12:30 – 13:30** Lunch
- 13:30 – 14:10** **Pharmaceutical market dynamics: Chasing growth in a challenging environment**
Jesper Larsen, Senior Strategic Consultant, IMS Health, Denmark
- Drivers and constraints in the pharmaceutical market place
 - Corporate positioning in a changing environment
 - Outlook: Pharma management implications in Europe and Nordics



- 14:10 – 14:50** **Medicon Valley – an attractive place for pharmaceutical production**
Christina Heje, Business Development Manager, Copenhagen Capacity, Denmark
- Competences in Medicon Valley
 - Benchmarking – considerations when choosing location site
 - Working culture
- 14:50 – 15:20** Coffee Break / Table Top Exhibition
- 15:20 – 16:05** **Science- and Risk Based GMP – Next Generation?**
Gert Mølgaard, Vice President – Process, NNE Pharmaplan, Denmark
- ISPE’s involvement in Implementation of ICH Q8, Q9 and Q10
 - PQLI - Product Quality Lifecycle Implementation
 - Quality by Design implementation challenges
- 16:05 – 16:50** **A GAMP Nordic Forum Annual Lecture: GAMP5 Update and Key Concepts**
Sion Wyn, Director, Conformity Ltd., UK
- Drivers for GAMP5
 - Key Concepts
 - Effective and Efficient compliance
- 16:50 – 17:00** **End of Conference**
Charlotte Enghave, PhD, Senior Consultant, NNE Pharmaplan, Chairman ISPE Nordic
- 17:15 – 18:00** **Annual General Meeting of ISPE Nordic Affiliate**
- **The Affiliate Chairman’s Report, Charlotte Enghave**, Chairman
 - **The Treasurer’s Report, Morten Munk**, Treasurer
 - **Election of Members to the Board**
 - **Any other business**
- 18:00 – 18:30** **Annual General Meeting of GAMP Nordic**
- **The Treasurer’s Report**
 - **Election of Members to the Steering Committee**
 - **Any other business**
- 19:00** Cocktails
- 19:30** **Annual Meeting Dinner** with entertainment

ISPE Nordic BOARD OF DIRECTORS 2007

Charlotte Enghave, *Chairman*, NNE Pharmaplan, Denmark
Sakari Salla, *Vice Chairman*, AstraZeneca, Sweden
Hans Sundin, *Past Chairman*, Loxia Consulting AB, Sweden
Morten Munk, *Treasurer*, CMC Biopharmaceuticals A/S, Denmark
Anders Bredeesen, *Secretary*, YIT Building Systems AS, Norway
Jonas Eriksson, NNE Pharmaplan, Sweden
Bo Norrman, Mälardalen University, Sweden
Wendy Klem, Sykehusapotekene ANS, Norway
Stefan Åkerman, Elomatic Pharmaceutical Engineering, Finland
Joachim Nordenberg, Advanced Medical Optics Uppsala, Sweden
Erik Bach, H. Lundbeck A/S, Denmark
Markus Karlsson, STERIS Corp./Pharma and Research, Finland
Tom Andersen, GE Healthcare, Norway
Linda Frederiksen, H. Lundbeck A/S, Denmark
Jukka Rantanen, Copenhagen University, Faculty of Pharmaceutical Sciences, Denmark



GAMP NORDIC STEERING COMMITTEE 2007

Anders Bredeesen, *Chairman*, YIT Building Systems AS, Norway
Niels Boye Petersen, *Secretary*, Siemens A/S, Building Technologies, Denmark
Hasse Greiner, Novo Nordisk A/S, Denmark
Anna Kälvemark, Pharmadule Emtunga AB, Sweden
Christer Fors, InformaIT Pharma Solutions, Sweden
Siri Segalstad, Segalstad Consulting as, Norway
Göran Slätt, AstraZeneca AB, Sweden
Jens Seest, Novo Nordisk A/S, Denmark
Peter Werner Christensen, *Deputy Representative*, NNE Pharmaplan, Denmark



REGISTRATION FORM – ISPE NORDIC ANNUAL MEETING
15 NOVEMBER 2007 – RADISSON SAS SCANDINAVIA HOTEL, DENMARK

Please fax or e-mail to Charlotte Enghave, NNE Pharmaplan, before 1 November 2007
Fax: +45 4444 3777 – E-mail CEn @nnepharmaplan.com

Name: Mr./ Ms.
Company: _____
Street: _____
Zip code: _____ City: _____ Country: _____
Tel.: _____ Fax: _____
E-mail: _____

- Member of ISPE – Personal Membership No. _____
 Non-Member of ISPE – Participation must include a 1-year membership of ISPE
 Student Academia Regulator

Please check the session(s) you wish to attend

- Conference (including lunch and coffee)
 Annual General Meeting (conference participants and/or members only)
 GAMP Nordic Annual Meeting
 Dinner (conference participants and/or members and/or invited guests only)

Please check if you wish to reserve

- Table Top for exhibition
 Dinner table (for eight persons) for your company and invited guests
 Dinner table and (number of) _____ conference seats for invited guests

Fees (payable in DKK)

- | | |
|---|----------|
| <input type="checkbox"/> Conference fee – Member of ISPE: | Euro 220 |
| <input type="checkbox"/> Conference fee – Non-Member*): | Euro 410 |
| <input type="checkbox"/> Conference fee – Academia/Regulatory Member | Euro 40 |
| <input type="checkbox"/> Conference fee – Academia/Regulatory Non-Member*): | Euro 70 |
| <input type="checkbox"/> Conference fee – Student Member: | Euro 20 |
| <input type="checkbox"/> Conference Fee – Students Non-Member*): | Euro 35 |
| <input type="checkbox"/> Annual Meeting Dinner including reception: | Euro 65 |
| <input type="checkbox"/> Dinner table for eight persons: | Euro 950 |
| <input type="checkbox"/> Table Top Exhibition: | Euro 500 |

Total due: _____

*) Includes 1-year membership of ISPE with all membership benefits – please visit www.ispe.org

Payment by

- An invoice issued to your company is the preferred way of payment.
Please specify invoicing address if different from the above address.

Visa/Master Card number: _____ Exp. Date: _____ CVV: _____

Date: _____ Signature: _____

Please provide an e-mail address for confirmation message.

ABOUT ISPE

ISPE (The International Society for Pharmaceutical Engineering) is the world's largest not-for-profit association dedicated to educating and advancing pharmaceutical manufacturing professionals and their industry.

Founded in 1980, today ISPE serves more than 23,000 members in more than 80 countries. We are an independent organization led by the world's top pharmaceutical manufacturing professionals. We provide an inviting and neutral environment for experts, technologists, regulators, consultants and students to exchange ideas and practical experience. As a vibrant community, ISPE's members work together to improve the industry, while helping each other make better choices, more quickly than ever before.

In addition to conducting educational conferences and training courses, ISPE also publishes a bi-monthly journal, *Pharmaceutical Engineering*, and a monthly membership newsletter, *ISPEAK*, to keep members abreast of the latest developments in the healthcare technology industries.

ISPE members have worked with the US Food & Drug Administration (FDA) on a variety of projects, which have assisted professionals by enhancing industry practices worldwide. ISPE and FDA collaborations include the SUPAC equipment addendum listing for which both the Agency and ISPE were awarded the Hammer Award by then-Vice President Al Gore's office, and the production of the *Pharmaceutical Engineering Baseline® Guide Series*. These Guides offer industry professionals a foundation from which to work in interpreting regulatory requirements for facility design and process implementation.

ABOUT THE NORDIC AFFILIATE

The Nordic affiliate was initiated in 2000. The Affiliate consists of the Nordic countries: Sweden, Norway, Denmark, Finland and Iceland. The Nordic membership has since grown to over 1,000 members with active regional representation in all Nordic countries.

The Nordic Affiliate Board of Directors is made up of the Chairman, Vice Chairman, Treasurer, Secretary, Past Chairman, and elected members. In addition, members can be co-opted for other duties. All members are volunteers and as such many have to fit in their ISPE activities with full-time jobs. The Nordic Board of Directors meets four to five times per year.

The Nordic Affiliate plans to have eight yearly events with a variety of the key ISPE Nordic focus areas. A visible, local member benefit for ISPE Nordic should include the opportunity to network and share experiences with colleagues in the local area.

www.ispe.org/nordic